REMARKS

Claims 4-8, 10-19, 21-22, 24-28 and 30-32 remain pending in this application with claims 4, 10, 11, 13, 19, 21, 22, 25 and 30-32 being amended and claims 9, 23 and 29 being cancelled by this response.

Objection to Claims 4, 11, 19 and 31

Claims 4, 11, 19 and 31 stand objected to for certain informalities. Claims 4, 11, 19 and 31 have been amended in accordance with the comments of the Examiner. In view of the amendments to claims 4, 11, 19 and 31 it is respectfully submitted that this objection is satisfied and should be withdrawn.

Objection to Claim 32 under 37 CFR 1.75(c)

Claim 32 stands objected to under 37 CFR 1.75(c) as being of improper dependent form. Claim 32 has been amended in accordance with the comments of the Examiner. In view of the amendments to claim 32 it is respectfully submitted that this objection is satisfied and should be withdrawn.

Rejection of Claims 4, 11, 13, 19, 21, 22 and 31 under 35 U.S.C. 112, second paragraph

Claims 4, 11, 13, 19, 21, 22 and 31 stand objected to under 35 U.S.C. 112, second paragraph as being indefinite. Claims 4, 11, 13, 19, 21, 22 and 31 have been amended in accordance with the comments of the Examiner. In view of the amendments to claims 4, 11, 13, 19, 21, 22 and 31 it is respectfully submitted that this objection is satisfied and should be withdrawn.

Rejection of Claims 21, 22, 24-26, 28 and 30-32 under 35 U.S.C. 102(b)

Claims 21, 22, 24-26, 28 and 30-32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Product Alert in light of Miner.

The present claimed invention recites a pharmaceutical composition for topical application to the site of insect bites and stings to relieve the itch, pain, and swelling associated therewith. The composition includes an effective amount of an abrasive ingredient and a carrier. The abrasive ingredient is selected from the group consisting of walnut shells, pumice, plastic materials, sand, stone, glass, seed shell, fruit shell, seed, metal, chitosan and ground crab shell. The carrier is selected from the group consisting of vegetable oil, fruit oil, soap, surfactant, lubricant, mineral oil, petrolatum, gel, lotion, emollient, white petroleum, beeswax, di-propylene glycol, gum, lubricating jelly and olive oil. The abrasive ingredient is ground to 35-60 mesh.

The Examiner states that "**a cosmetic** sold by Origins Natural Resources (ONR) named 'Never a Dull Moment' (NDM) contains . . .", and goes on to name some of the ingredients also contained in the **pharmaceutical composition** of the present invention. The Examiner concludes in her 102(b) rejection that since **the compositions are the same**, a mere different use for a known composition is not patentable. See In re Hack, 245 F.2d 246, 248, 114 U.S.P.Q. 161, 163 (CCPA 1957). It is respectfully submitted that the compositions, of NDM and the instant pharmaceutical composition for treating insect bites and stings, **are not the same**.

Firstly, Applicant respectfully submits that the cosmetic product sold by ONR under the trademark NDM is specially formulated for **cosmetic purposes only** and is not usable as a pharmaceutical composition for treating insect bites and stings. The pharmaceutical composition of the present claimed invention is specifically designed and formulated to quickly stop and interrupt or disrupt the insects' venom sequence.

Specifically, the claimed pharmaceutical composition of the present claimed invention has the exact mixture of ingredients that will:

a) abrade the top layer of skin, thereby encouraging circulation of blood to help push venom toward the skin surface;

b) open skin pores to allow insect venom to be removed;

c) draw on the surface skin pores in order to pull the venom to the surface;

d) neutralize the insect venom; and

e) sanitize and speed the healing process of the traumatized area.

Cosmetic products such as Origin's NDM is not specifically formulated to remove or treat insect bites and stings, and thus, would not be usable to accomplish identical treatment results. In fact, the **many additional (cosmetic) ingredients contained in NDM** (e.g. Butylenes glycol, lecithin, behenyl betaine, glycerin, propylene glycol stearate, polysorbate 20, sodium chloride, dimethyl isosorbide, etc.), would interfere with the ability to open the pores and neutralize the venom or adequately sanitize the traumatized area. The makers of NDM have not and do not recommend that their product be used for the mitigation of insect bites and stings. The claims remaining in the application have been clarified so that the claimed invention is directed to a pharmaceutical composition which contains a formulated and effective amount of an abrasive ingredient and a carrier; which relieves the itch, pain and swelling due to insect bites and stings.

In sum, the cited cosmetic related prior art does not disclose the same composition disclosed herein for a pharmaceutical use. In view of the amendments to the claims and the above remarks setting forth the distinguishing features of the present claimed invention, it is respectfully submitted that the presently disclosed inventive pharmaceutical composition is not "anticipated" under 35 U.S.C. 102(b) by Product Alert in light of Miner.

It is well settled law that a proper 102 "anticipation" requires disclosure in a single prior art reference of **each and every element** presently claimed. See for example Leinoff v. Milona & Sons, 220 U.S.P.Q.845 (C.A.F.C., 1984); R.C.A. Corp. v. Applied Digital Data Systems, Inc.221 U.S.P.Q. 385 (C.A.F.C., 1984); W.L.Gore & Associates, Inc. v. Garlock 220 U.S.P.Q. 303 (C.A.F.C., 1983). Since there are numerous additional ingredients in NDM, which result in a totally different function and use as well as inhibiting the effectiveness for use to perform the objective of the present claimed invention, it is respectfully submitted that the pharmaceutical composition of the present claimed invention cannot be said to be "anticipated" by Origin's NDM cosmetic composition.

Rejection of Claims 4-19 and 21-32 under 35 U.S.C. 103(a)

Claims 4-19 and 21-32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Product Alert (1998) (i.e. NDM – a cosmetic composition), in light of Miner (2002) and in view of Tseng '634.

Again, it is submitted that Product Alert (1998) (i.e. NDM – a cosmetic composition) is a cosmetic composition with numerous additional (cosmetic) ingredients contained therein (e.g. Butylenes glycol, lecithin, behenyl betaine, glycerin, propylene glycol stearate, polysorbate 20, sodium chloride, dimethyl isosorbide, etc.), which would actually interfere with the ability to open the pores and neutralize the venom in the traumatized area. The makers of that cosmetic composition did not direct that the composition could also be used as a pharmaceutical composition, and one skilled in the art, looking at that disclosure, would not in any way be directed to using it to treat insect bites and stings, or any similar pharmaceutical use.

Tseng et al. were cited to disclose polymers for cosmetic use which were created to pass through mesh sizes anywhere between 40 to 350 mesh. It is respectfully submitted that Tseng et al. add nothing to Product Alert that would increase the ability of Product Alert to open the pores and neutralize the venom in the traumatized area and thus perform the objective of the present claimed invention. Furthermore, it is respectfully submitted that Tseng et al. is directed to a substance acting as a conditioner or skin base and neither discloses nor suggests a pharmaceutical composition which would be directed for use in treating insect bites and stings, or any similar pharmaceutical use.

In view of the above remarks it is therefore respectfully submitted that this Tseng et al. adds nothing in combination with Product Alert which would make the present claimed

invention unpatentable. It is thus further respectfully submitted that this rejection is satisfied and should be withdrawn.

Rejection of Claims 4-19 and 21-32 under 35 U.S.C. 103(a)

Claims 4-19 and 21-32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Greene in view of Tseng '634.

It is respectfully submitted that neither Greene nor Tseng '634, alone or in combination, would make obvious to one skilled in the art the exact pharmaceutical composition that is now, for the first time, disclosed and claimed in the present application. The inventor submits that if the ingredients cited by the Examiner as being disclosed by these prior art references (see page 13, 2nd to last paragraph of the Office Action) were in fact mixed together, the salt would instantly go into solution and would no longer provide the **inventive abrasive effect that occurs with the present claimed pharmaceutical composition.** Meat tenderizer alone cannot provide the inventive pharmaceutical results that the claims in the instant invention provide. Meat tenderizer, for instance, does not have the ability to draw venom from skin pores and has no venom neutralizing ingredients or even sanitizing/healing abilities. Human/animal reactions and dynamics of insect bites and stings have been long studied and documented (e.g. Dr. Greene), and internal and external remedies have been scientifically and informally applied, however, no prior "ordinary skilled person in the art" has yet developed a pharmaceutical composition in any way similar to the ones herein claimed which have all of the benefits outlined again, below:

1) abrade the top layer of skin, thereby encouraging circulation of blood to help push venom toward the skin surface;
2) open skin pores to allow insect venom to be removed;
3) draw on the surface skin pores in order to pull the venom to the surface;

4) neutralize the insect venom; and

5) sanitize and speed the healing process of the traumatized area.

As the Court in Hughes Aircraft Co. v. United States, 215 U.S.P.Q. 787, 804 (Ct. Claims, 1982) noted "In any consideration of obviousness, it is always necessary to be vigilant against the possibility of hindsight creeping into the analysis. One way that the courts have guarded against hindsight is by insisting that the reason for making the suggested changes be apparent **at the time the invention was made** to a person of ordinary skill in the art". As the 7th Circuit Court of Appeals concluded in Novo Industri A/S v. Travenol Laboratories, Inc., 215 U.S.P.Q. 412, 417 (7th Cir., 1982), "'Obvious to try' is not the same as 'obviousness' . . . Travenol's argument demonstrates that in hindsight there existed a route to a particular result. To argue that either the route or the result was obvious is comparable to arguing the obviousness of Columbus' discovery of America from the fact of its discovery."

It is also submitted that all meat tenderizers do not include papain, and those meat tenderizers having a digestive enzyme or papain, contain a very small amount in comparison to the pharmaceutical composition claimed in the instant application. Although the cited meat tenderizer having a digestive enzyme or papain may have some effect on the traumatized area, it would not have enough of an effect to actually and safely remove the venom as does the specific combination of ingredients contained in the composition shown in this amended application.

It is also recognized by the Patent Office that in making a 35 U.S.C. 103 obviousness rejection, that it is not proper to use prohibited hindsight to form the previously un-obvious invention. See In re Piasecki, 745 F2d 1468, 223 U.S.P.Q. 785, 789 (Fed Cir. 1984); In re Rinehart, 531 F2d. 1048, 189 U.S.P.Q. 143, 148-149. As the Court

in In re Piasecki noted on page 789, the fact that "the prior teachings 'point in the direction of the subject matter . . . is not the standard of 35 U.S.C. 103".

In the Examiner's first Office Action, however, various teachings in distinctly different fields:

- in the cosmetic field (Origins Natural Resources 'Never a Dull Moment');
- in the polymer field (Tseng '634); and
- in the medical "self-help" field (Dr. Greene),

have been combined together like a hind sighted puzzle and it has been concluded that it would have been obvious to one skilled in the art to create the pharmaceutical composition to relieve the itch, pain, and swelling associated with insect bites and stings comprising an effective amount of an abrasive ingredient and a carrier both selected from a specific group of ingredients.

In sum, there is no factual showing that one skilled in the art of any one of the 3 above listed differing fields would have been directed to create the pharmaceutical composition disclosed in the instant application. Since Green and Tseng '634 have been fully distinguished above, to hold that any of the claims are "103 obvious", should not be maintained.

In view of the above remarks it is therefore respectfully submitted that Green, when taken alone or in combination with Tseng et al. do not make the present claimed invention unpatentable. It is thus further respectfully submitted that this rejection is satisfied and should be withdrawn.

In light of all the above respectfully submitted remarks and distinguishing features, together with the case citations, the applicant believes that the herein amended application

containing claims 4-8, 10-19, 21-22, 24-28 and 30-32 patently distinguish over the cited prior art. In light of the clear inventive concepts of the present application, as set forth above, the applicant accordingly requests that Examiner Patten now reconsider the application and allow it, as amended, to pass to issue.

No fee is believed due with this response. However, should a fee be due please charge the fee to Deposit Account No. 500716.

Based upon the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner consider necessary or desirable any formal changes anywhere in the specification, claims and/or drawings, then it is respectfully asked that such changes be made by Examiner's amendment, if the Examiner feels this would facilitate passage of the case to issuance.

Alternatively, should the Examiner have any questions, comments, or feel that a personal discussion might be helpful in advancing this case to allowance and issuance, she is cordially invited to contact Mr. Jack J. Schwartz at 1350 Broadway, Suite 1507, New York, New York 10018, Tel. No. (212) 971-9017, so that the present application can receive

an early notice of allowance. The address and telephone number for Jack J. Schwartz stated above is as listed on the original Power of Attorney.

In light of the foregoing, the application is now believed to be in proper form for allowance of all claims and notice to that effect is earnestly solicited.

Respectfully submitted,

Patrick Kennedy

By_____
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Date: October 17, 2002

Version with Marking to Show Changes Made

IN THE SPECIFICATION

Please amend the specification as indicated below.

Please replace the paragraph beginning on Page 10, line 3 with the following paragraph:

Other inert ingredients that may be used in this invention include: vegetable and fruit oils, soaps, surfactants, lubricants, mineral oils, petrolatum, gels, lotions, emollients, white petroleum, beeswax, di-propylene glycol, gums, lubricating jelly and olive oils. Other active ingredients that may be used in this invention include: menthol, Benadryl, diphenhydramine hydrochloride, germicidal disinfectants, aloe/aloe vera, silicone, antiseptic preparations, antimicrobial agents such as PCMX, broad spectrum surface disinfectants, lidocaine, boric acid/borates, vitamins, oils from flowers, plants or animals, Neosporin, hydrocortisone cream/acetate, swelling and pain reducers, benzocaine, isobutene, hydrogen peroxide, iodine, zinc acetate, ammonia hydroxide, citronella, peppermint oil, analgesic/antihistamine ingredients, calamine, camphor, clove oil and methylparaben. It is preferred that the pharmaceutical composition be in the form of a cream or lotion for easy application and adhesion to the affected area, although a pharmaceutical composition in other forms, such as powder, could be used. If stored in powdered form, a small amount of water can be mixed with the powdered composition before use to improve the adhesive and abrasive qualities of the pharmaceutical composition.

Version with Marking to Show Changes Made

IN THE CLAIMS

Please cancel claims 9, 23 and 29 without prejudice or disclaimer.

Please amend claims 4, 10, 11, 13, 19, 21, 22, 25 and 30-32 as follows:

4. (Amended) A pharmaceutical composition for topical application to the site of insect bites and stings to relieve the itch, pain, and swelling associated therewith, comprising an effective amount of an abrasive ingredient and a carrier;

wherein said abrasive ingredient is selected from the group [thereof] consisting of walnut shells, pumice, plastic materials, sand [or], stone, glass, seed [or] shell, fruit [shells] shell, [seeds] seed, metal, [any sort of brush, abrasive applicators,] chitosan and ground crab shell [shells, all at 35-60 mesh, and a carrier for said active ingredient suitable for topical application to the human skin,];

wherein said carrier is selected from the group consisting of vegetable oil, [and] fruit [oils] oil, [soaps] soap, [surfactants] surfactant, [lubricants] lubricant, mineral [oils] oil, petrolatum, [gels lotions] gel, lotion, [emollients] emollient, white petroleum, beeswax, di-propylene glycol, [gums] gum, lubricating jelly and olive [oils] oil; and

wherein said abrasive ingredient is ground to 35-60 mesh.

10. (Amended) The pharmaceutical composition for topical application according to claim 4, wherein the composition additionally includes an [anesthetic] active ingredient.

11. (Amended) The pharmaceutical composition for topical application according to claim 10 wherein the [anesthetic] active ingredient is selected from the group

consisting of menthol, Benadryl, diphenhydramine hydrochloride, germicidal disinfectants, [aloe/aloe vera] aloe, aloe vera, silicone, antiseptic preparations, antimicrobial agents such as [PCMX] triclosan, broad spectrum surface disinfectants, lidocaine, boric [acid/borates] acid, borates, vitamins, oils from flowers, plants or animals, Neosporin, hydrocortisone [cream/acetate] cream, hydrocortisone acetate, swelling and pain reducers, benzocaine, isobutene, hydrogen peroxide, iodine, zinc acetate, ammonia hydroxide, citronella, peppermint oil, [analgesic/antihistamine] analgesic ingredients, antihistamine ingredients, calamine, camphor, clove oil and methylparaben.

13. (Amended) [The] A pharmaceutical composition for topical application to the site of insect bites and stings to relieve the itch, pain, and swelling associated therewith, comprising an effective amount of an abrasive ingredient; and effective amount of an anti-itch enzyme; said abrasive ingredient and said anti-itch enzyme being dispersed in a water based pharmaceutical carrier comprising effective amounts of polysorbate 60; isopropyl palmitate; pentaerythrityl [tetracapryate/caprate] tetracapryate, pentaerythrityl caprate; poliwax emulsifying wax NF; cetrearyl alcohol; ethyl alcohol; sodium hydroxide; NaHCO3; and propylene glycol.

19. (Amended) The pharmaceutical composition for topical application according to claim 18, wherein the [anesthetic] active ingredient is selected from the group consisting of menthol, Benadryl, diphenhydramine hydrochloride, germicidal disinfectants, [aloe/aloe vera] aloe, aloe vera, silicone, antiseptic preparations, antimicrobial agents such as [PCMX] triclosan, broad spectrum surface disinfectants, lidocaine, boric [acid/borates] acid, borates, vitamins, oils from flowers, plants or animals, Neosporin, hydrocortisone [cream/acetate] cream, hydrocortisone acetate, swelling and pain reducers, benzocaine, isobutene, hydrogen peroxide, iodine, zinc acetate, ammonia hydroxide, citronella, peppermint oil, [analgesic/antihistamine] analgesic ingredients, antihistamine ingredients, calamine, camphor, clove oil and methylparaben.

21. (Amended) A pharmaceutical composition for topical application to the site of insect bites and stings to relieve the itch, pain, and swelling associated therewith, comprising an effective amount of an abrasive ingredient and a carrier for said [active] abrasive ingredient suitable for topical application to the [human skin] site of the insect bite or sting.

22. (Amended) The composition according to Claim [22] 21, wherein the abrasive ingredient is [at] selected from the group consisting of walnut [shells] shell, pumice, plastic [materials] material, ground sand, [or] ground stone, ground glass, seed shell, [or] fruit [shells] shell, [seeds] seed, metal, [any sort of brush, abrasive applicators,] chitosan [or] and ground crab [shells] shell; and wherein said abrasive ingredient is ground to 35-60 mesh.

25. (Amended) The composition according to Claim 21, wherein [an itch-reducing amount of an enzyme chosen from the group consisting of papain, subtilisin, and pancreatin, is added to the pharmaceutical composition for application to the surface of the skin proximate to said insect bite or sting] the carrier is selected from the group consisting of vegetable oil, fruit oil, soap, surfactant, lubricant, mineral oil, petrolatum, gel, lotion, emollient, white petroleum, beeswax, di-propylene glycol, gum, lubricating jelly and olive oil.

30. (Amended) The pharmaceutical composition for topical application according to claim 21, wherein the composition additionally includes an [anesthetic] active ingredient.

31. (Amended) The pharmaceutical composition for topical application according to claim [29] 30, wherein the [anesthetic] active ingredient is selected from the group consisting of menthol, Benadryl, diphenhydramine hydrochloride, germicidal disinfectants, [aloe/aloe vera] aloe, aloe vera, silicone, antiseptic preparations, antimicrobial agents such as [PCMX] triclosan, broad spectrum surface disinfectants, lidocaine, boric [acid/borates] acid, borates, vitamins, oils from flowers, plants or animals, Neosporin, hydrocortisone [cream/acetate] cream, hydrocortisone acetate, swelling and pain reducers, benzocaine, isobutene, hydrogen peroxide, iodine, zinc acetate, ammonia hydroxide, citronella, peppermint oil, [analgesic/antihistamine] analgesic ingredients, antihistamine ingredients, calamine, camphor, clove oil and methylparaben.

32. (Amended) The pharmaceutical composition according to claim 22 wherein said [abrasive ingredient and said anti-itch enzyme are applied as a solution in an aqueous pharmaceutical carrier] composition further includes an aqueous pharmaceutical carrier.

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Date of Deposit October 17, 2002

Jackie Jay Schwartz
(Signature of person mailing paper or fee)